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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,357	12/12/2003	Yijia P. Bao	02-1227-A	2590
20306 7590 01/31/2007 MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606			EXAMINER SISSON, BRADLEY L	
			ART UNIT 1634	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
31 DAYS			01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/735,357

Applicant(s)

BAO ET AL.

Examiner

Bradley L. Sisson

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-167 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-167 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Upon consideration of applicant's argument submitted in their response of 02 October 2006, and upon consideration of the amendment to claims, the preceding restriction/election requirement is hereby vacated.

2. A new election follows.

3. This application contains claims directed to the following patentably distinct species:

I. Method for

A. Detecting presence

1. One target nucleic acid

a. Target nucleic acid comprises

- i. Genomic DNA
- ii. Genomic RNA
- iii. Expressed RNA
- iv. Plasmid DNA
- v. Mitochondrial DNA
- vi. Cellular organelle DNA other than mitochondrial
- vii. Viral DNA
- viii. Viral RNA
- ix. Mixture of two of i- viii
- x. Mixture of more than two of i-viii

b. Sample is contacted

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- i. With detector probe so that a nucleic acid target presenting sample hybridizes with the detector oligonucleotides on the detector probe, and the nucleic acid target bound to the detector probe is then contacted with the substrate so that the nucleic acid target hybridizes with the capture oligonucleotides on the substrate
 - ii. With the substrate so that a nucleic acid target present in the sample hybridizes with a capture oligonucleotide, and the nucleic acid target bound to the capture oligonucleotide is then contacted with the detector probe so that the nucleic acid target hybridizes with the detector oligonucleotides on the detector probe
 - iii. Simultaneously with the detector probe and the substrate
- c. The detection label
- i. Allows detection by
 - a) Photonic means
 - b) Electronic means
 - c) Acoustic means
 - d) Opto-acoustic means
 - e) Gravity
 - f) Electro-chemical means
 - g) Electro-optic means

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- h) Mass-spectrometric means
- i) Enzymatic means
- j) Chemical means
- k) Biochemical means
- l) Physical means
- ii. Label on detector oligonucleotide (part of detector probe) is:
 - a) Fluorescent
 - b) Luminescent
 - c) Phosphorescent
 - d) Radioactive
 - e) A nanoparticle
 - i) Is made of
 - (a) Noble metal
 - (i) Gold
 - (ii) Silver
 - (iii) Other than a noble metal
 - (iv) Material that is conductor of electricity
 - ii) Detecting

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- (a) Light scattered
 - (b) Contacting substrate with silver stain
 - (c) Observation with an optical scanner
 - (d) Observation with a flatbed scanner
 - (e) A change in conductivity
 - iii) Oligonucleotides are
 - (a) Located between electrodes
 - (i) Electrodes made of gold
 - (ii) Electrodes not made of gold
 - f) A dendrimer
 - g) A molecular aggregate
 - h) A quantum dot
 - i) A bead
- d. Higher biological complexity is
 - i. Greater than 50,000
 - ii. Between about 50,000 and about 50,000,000,000
- e. Target nucleic acid is

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- i. A portion of a gene of a biological organism
- ii. A portion of a gene of a *Staphylococcus* bacterium
 - a) *S. aureus*
 - b) *S. haemolyticus*
 - c) *S. epidermidis*
 - d) *S. lugdunensis*
 - e) *S. hominis*
 - f) *S. saprophyticus*
 - g) Portion of *Tuf* gene
 - h) Portion of *femA* gene
 - i) Portion of 16S rRNA gene
 - j) Portion of *hsp60* gene
 - k) Portion of *sodA* gene
 - l) Portion of *mecA* gene
- f. Target nucleic acid comprises the sequence set forth in one of SEQ ID NO: 17 through SEQ ID NO.: 78
- g. The detection oligonucleotides comprise the sequence set forth in one of SEQ ID NO: 17 to SEQ ID NO: 78
- h. The capture oligonucleotide comprises the sequence set forth in one of SEQ ID NO: 17 to 78.

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2. More than one target nucleic acid
 - a. Target nucleic acid comprises
 - i. Genomic DNA
 - ii. Genomic RNA
 - iii. Expressed RNA
 - iv. Plasmid DNA
 - v. Mitochondrial DNA
 - vi. Cellular organelle DNA other than mitochondrial
 - vii. Viral DNA
 - viii. Viral RNA
 - ix. Mixture of two of i- viii
 - x. Mixture of more than two of i-viii
 - b. Sample is contacted
 - i. With detector probe so that a nucleic acid target presenting sample hybridizes wit the detector oligonucleotides on the detector probe, and the nucleic acid target bound to the detector probe is then contacted wit the substrate so that the nucleic acid target hybridizes with the capture oligonucleotides on the substrate
 - ii. With the substrate so that a nucleic acid target present in the sample hybridizes with a capture oligonucleotide, and the nucleic acid target bound to the capture oligonucleotide is

then contacted with the detector probe so that the nucleic acid target hybridizes with the detector oligonucleotides on the detector probe

iii. Simultaneously with the detector probe and the substrate

c. The detection label

i. Allows detection by

- a) Photonic means
- b) Electronic means
- c) Acoustic means
- d) Opto-acoustic means
- e) Gravity
- f) Electro-chemical means
- g) Electro-optic means
- h) Mass-spectrometric means
- i) Enzymatic means
- j) Chemical means
- k) Biochemical means
- l) Physical means

ii. Label on detector oligonucleotide (part of detector probe) is:

- a) Fluorescent
- b) Luminescent

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- c) Phosphorescent
- d) Radioactive
- e) A nanoparticle
 - i) Is made of
 - (a) Noble metal
 - (i) Gold
 - (ii) Silver
 - (iii) Other than a noble metal
 - (iv) Material that is conductor of electricity
 - ii) Detecting
 - (a) Light scattered
 - (b) Contacting substrate with silver stain
 - (c) Observation with an optical scanner
 - (d) Observation with a flatbed scanner
 - (e) A change in conductivity
 - iii) Oligonucleotides are

- (a) Located between electrodes
 - (i) Electrodes made of gold
 - (ii) Electrodes not made of gold
 - f) A dendrimer
 - g) A molecular aggregate
 - h) A quantum dot
 - i) A bead
- d. Higher biological complexity is
 - i. Greater than 50,000
 - ii. Between about 50,000 and about 50,000,000,000
- e. Target nucleic acid is
 - i. A portion of a gene of a biological organism
 - ii. A portion of a gene of a *Staphylococcus* bacterium
 - a) *S. aureus*
 - b) *S. haemolyticus*
 - c) *S. epidermidis*
 - d) *S. lugdunensis*
 - e) *S. hominis*
 - f) *S. saprophyticus*
 - g) Portion of *Tuf* gene

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- h) Portion of *femA* gene
 - i) Portion of 16S rRNA gene
 - j) Portion of *hsp60* gene
 - k) Portion of *sodA* gene
 - l) Portion of *mecA* gene
- f. Target nucleic acid comprises the sequence set forth in one of SEQ ID NO: 17 through SEQ ID NO.: 78
- g. The detection oligonucleotides comprise the sequence set forth in one of SEQ ID NO: 17 to SEQ ID NO: 78
- h. The capture oligonucleotide comprises the sequence set forth in one of SEQ ID NO: 17 to 78.

B. Detecting absence of

- a. Target nucleic acid comprises
 - i. Genomic DNA
 - ii. Genomic RNA
 - iii. Expressed RNA
 - iv. Plasmid DNA
 - v. Mitochondrial DNA
 - vi. Cellular organelle DNA other than mitochondrial
 - vii. Viral DNA

- viii. Viral RNA
 - ix. Mixture of two of i- viii
 - x. Mixture of more than two of i-viii
- b. Sample is contacted
 - i. With detector probe so that a nucleic acid target presenting sample hybridizes wit the detector oligonucleotides on the detector probe, and the nucleic acid target bound to the detector probe is then contacted wit the substrate so that the nucleic acid target hybridizes with the capture oligonucleotides on the substrate
 - ii. With the substrate so that a nucleic acid target present in the sample hybridizes with a capture oligonucleotide, and the nucleic acid target bound to the capture oligonucleotide is then contacted with the detector probe so that the nucleic acid target hybridizes with the detector oligonucleotides on the detector probe
 - iii. Simultaneously with the detector probe and the substrate
- c. The detection label
 - i. Allows detection by
 - a) Photonic means
 - b) Electronic means
 - c) Acoustic means

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- d) Opto-acoustic means
- e) Gravity
- f) Electro-chemical means
- g) Electro-optic means
- h) Mass-spectrometric means
- i) Enzymatic means
- j) Chemical means
- k) Biochemical means
- l) Physical means
- ii. Label on detector oligonucleotide (part of detector probe) is:
 - a) Fluorescent
 - b) Luminescent
 - c) Phosphorescent
 - d) Radioactive
 - e) A nanoparticle
 - i) Is made of
 - (a) Noble metal
 - (i) Gold
 - (ii) Silver
 - (iii) Other than a noble metal

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- (iv) Material that is
conductor of
electricity
 - ii) Detecting
 - (a) Light scattered
 - (b) Contacting substrate with
silver stain
 - (c) Observation with an optical
scanner
 - (d) Observation with a flatbed
scanner
 - (e) A change in conductivity
 - iii) Oligonucleotides are
 - (a) Located between electrodes
 - (i) Electrodes made of
gold
 - (ii) Electrodes not made
of gold
- f) A dendrimer
- g) A molecular aggregate
- h) A quantum dot
- i) A bead

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- d. Higher biological complexity is
 - i. Greater than 50,000
 - ii. Between about 50,000 and about 50,000,000,000
- e. Target nucleic acid is
 - i. A portion of a gene of a biological organism
 - ii. A portion of a gene of a *Staphylococcus* bacterium
 - a) *S. aureus*
 - b) *S. haemolyticus*
 - c) *S. epidermidis*
 - d) *S. lugdunensis*
 - e) *S. hominis*
 - f) *S. saprophyticus*
 - g) Portion of *Tuf* gene
 - h) Portion of *femA* gene
 - i) Portion of 16S rRNA gene
 - j) Portion of *hsp60* gene
 - k) Portion of *sodA* gene
 - l) Portion of *mecA* gene
- f. Target nucleic acid comprises the sequence set forth
in one of SEQ ID NO: 17 through SEQ ID NO.: 78

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- g. The detection oligonucleotides comprise the sequence set forth in one of SEQ ID NO: 17 to SEQ ID NO: 78
 - h. The capture oligonucleotide comprises the sequence set forth in one of SEQ ID NO: 17 to 78.
- 2. More than one target nucleic acid.
 - a. Target nucleic acid comprises
 - i. Genomic DNA
 - ii. Genomic RNA
 - iii. Expressed RNA
 - iv. Plasmid DNA
 - v. Mitochondrial DNA
 - vi. Cellular organelle DNA other than mitochondrial
 - vii. Viral DNA
 - viii. Viral RNA
 - ix. Mixture of two of i- viii
 - x. Mixture of more than two of i-viii
 - b. Sample is contacted
 - i. With detector probe so that a nucleic acid target presenting sample hybridizes with the detector oligonucleotides on the detector probe, and the nucleic acid target bound to the detector probe is then contacted with the substrate so that the

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nucleic acid target hybridizes with the capture
oligonucleotides on the substrate

- ii. With the substrate so that a nucleic acid target present in the sample hybridizes with a capture oligonucleotide, and the nucleic acid target bound to the capture oligonucleotide is then contacted with the detector probe so that the nucleic acid target hybridizes with the detector oligonucleotides on the detector probe
 - iii. Simultaneously with the detector probe and the substrate
- c. The detection label
- i. Allows detection by
 - a) Photonic means
 - b) Electronic means
 - c) Acoustic means
 - d) Opto-acoustic means
 - e) Gravity
 - f) Electro-chemical means
 - g) Electro-optic means
 - h) Mass-spectrometric means
 - i) Enzymatic means
 - j) Chemical means
 - k) Biochemical means

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- l) Physical means
- ii. Label on detector oligonucleotide (part of detector probe) is:
 - a) Fluorescent
 - b) Luminescent
 - c) Phosphorescent
 - d) Radioactive
 - e) A nanoparticle
 - i) Is made of
 - (a) Noble metal
 - (i) Gold
 - (ii) Silver
 - (iii) Other than a noble metal
 - (iv) Material that is conductor of electricity
 - ii) Detecting
 - (a) Light scattered
 - (b) Contacting substrate with silver stain

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- (c) Observation with an optical scanner
 - (d) Observation with a flatbed scanner
 - (e) A change in conductivity
 - iii) Oligonucleotides are
 - (a) Located between electrodes
 - (i) Electrodes made of gold
 - (ii) Electrodes not made of gold
- f) A dendrimer
- g) A molecular aggregate
- h) A quantum dot
- i) A bead
- d. Higher biological complexity is
 - i. Greater than 50,000
 - ii. Between about 50,000 and about 50,000,000,000
- e. Target nucleic acid is
 - i. A portion of a gene of a biological organism
 - ii. A portion of a gene of a *Staphylococcus* bacterium
 - a) *S. aureus*

- b) *S. haemolyticus*
 - c) *S. epidermidis*
 - d) *S. lugdunensis*
 - e) *S. hominis*
 - f) *S. saprophyticus*
 - g) Portion of *Tuf* gene
 - h) Portion of *femA* gene
 - i) Portion of 16S rRNA gene
 - j) Portion of *hsp60* gene
 - k) Portion of *sodA* gene
 - l) Portion of *mecA* gene
- f. Target nucleic acid comprises the sequence set forth in one of SEQ ID NO: 17 through SEQ ID NO.: 78
- g. The detection oligonucleotides comprise the sequence set forth in one of SEQ ID NO: 17 to SEQ ID NO: 78
- h. The capture oligonucleotide comprises the sequence set forth in one of SEQ ID NO: 17 to 78.
- i. Method used to distinguish between two or more species of a common genus
- a) Species differ by two or more non-consecutive nucleotides

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b) Species differ by two or more consecutive nucleotides

c) Species differ by at least one nucleotide

C. Identifying a single nucleotide polymorphism

a. Target nucleic acid comprises

- i. Genomic DNA
- ii. Genomic RNA
- iii. Expressed RNA
- iv. Plasmid DNA
- v. Mitochondrial DNA
- vi. Cellular organelle DNA other than mitochondrial
- vii. Viral DNA
- viii. Viral RNA
- ix. Mixture of two of i- viii
- x. Mixture of more than two of i-viii

b. Sample is contacted

- i. With detector probe so that a nucleic acid target presenting sample hybridizes with the detector oligonucleotides on the detector probe, and the nucleic acid target bound to the detector probe is then contacted with the substrate so that the nucleic acid target hybridizes with the capture oligonucleotides on the substrate

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- ii. With the substrate so that a nucleic acid target present in the sample hybridizes with a capture oligonucleotide, and the nucleic acid target bound to the capture oligonucleotide is then contacted with the detector probe so that the nucleic acid target hybridizes with the detector oligonucleotides on the detector probe
 - iii. Simultaneously with the detector probe and the substrate
- c. The detection label
- i. Allows detection by
 - a) Photonic means
 - b) Electronic means
 - c) Acoustic means
 - d) Opto-acoustic means
 - e) Gravity
 - f) Electro-chemical means
 - g) Electro-optic means
 - h) Mass-spectrometric means
 - i) Enzymatic means
 - j) Chemical means
 - k) Biochemical means
 - l) Physical means
 - ii. Label on detector oligonucleotide (part of detector

probe) is:

- a) Fluorescent
- b) Luminescent
- c) Phosphorescent
- d) Radioactive
- e) A nanoparticle
 - i) Is made of
 - (a) Noble metal
 - (i) Gold
 - (ii) Silver
 - (iii) Other than a noble metal
 - (iv) Material that is conductor of electricity
 - ii) Detecting
 - (a) Light scattered
 - (b) Contacting substrate with silver stain
 - (c) Observation with an optical scanner

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(d) Observation with a flatbed scanner

(e) A change in conductivity

iii) Oligonucleotides are

(a) Located between electrodes

(i) Electrodes made of gold

(ii) Electrodes not made of gold

f) A dendrimer

g) A molecular aggregate

h) A quantum dot

i) A bead

d. Higher biological complexity is

i. Greater than 50,000

ii. Between about 50,000 and about 50,000,000,000

D. Identifying more than one single nucleotide polymorphism

a. Target nucleic acid comprises

i. Genomic DNA

ii. Genomic RNA

iii. Expressed RNA

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- iv. Plasmid DNA
 - v. Mitochondrial DNA
 - vi. Cellular organelle DNA other than mitochondrial
 - vii. Viral DNA
 - viii. Viral RNA
 - ix. Mixture of two of i- viii
 - x. Mixture of more than two of i-viii
- b. Sample is contacted
- i. With detector probe so that a nucleic acid target presenting sample hybridizes with the detector oligonucleotides on the detector probe, and the nucleic acid target bound to the detector probe is then contacted with the substrate so that the nucleic acid target hybridizes with the capture oligonucleotides on the substrate
 - ii. With the substrate so that a nucleic acid target present in the sample hybridizes with a capture oligonucleotide, and the nucleic acid target bound to the capture oligonucleotide is then contacted with the detector probe so that the nucleic acid target hybridizes with the detector oligonucleotides on the detector probe
 - iii. Simultaneously with the detector probe and the substrate
- c. The detection label

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i. Allows detection by

- a) Photonic means
- b) Electronic means
- c) Acoustic means
- d) Opto-acoustic means
- e) Gravity
- f) Electro-chemical means
- g) Electro-optic means
- h) Mass-spectrometric means
- i) Enzymatic means
- j) Chemical means
- k) Biochemical means
- l) Physical means

ii. Label on detector oligonucleotide (part of detector probe) is:

- a) Fluorescent
- b) Luminescent
- c) Phosphorescent
- d) Radioactive
- e) A nanoparticle
 - i) Is made of
 - (a) Noble metal

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- (i) Gold
 - (ii) Silver
 - (iii) Other than a noble metal
 - (iv) Material that is conductor of electricity
- ii) Detecting
 - (a) Light scattered
 - (b) Contacting substrate with silver stain
 - (c) Observation with an optical scanner
 - (d) Observation with a flatbed scanner
 - (e) A change in conductivity
- iii) Oligonucleotides are
 - (a) Located between electrodes
 - (i) Electrodes made of gold
 - (ii) Electrodes not made of gold

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- f) A dendrimer
- g) A molecular aggregate
- h) A quantum dot
- i) A bead

- d. Higher biological complexity is
 - i. Greater than 50,000
 - ii. Between about 50,000 and about 50,000,000,000

4. The species are independent or distinct because 1) the methods can comprise patentably distinct components, and different method steps, and result in different end products; and 2) because of their different classification; and 3) because of their different searches. Methods involving an enzyme and viral nucleic acid are classified in Class 435, subclass 5, while non-viral nucleic acids assays involving an enzyme are classified in class 435, subclass 6. Nucleic acids assays that do not involve any enzyme are classified in Class 436, subclass 94.

5. Species directed to the analysis of optical signals would require a search of Class 436, subclass 800, while species drawn to the use of electric fields would require a search of Class 204, subclass 450. Species requiring the use of immobilized nucleic acids would require a search of Class 435, subclass 287.2

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

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7. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

10. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Sequence Restriction Requirement Applicable to Elected Species

In addition, detailed above read on patentably distinct Groups drawn to multiple nucleic acid fragments and polypeptide fragments found in multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to nucleotide sequences or cells/vectors comprising

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same or methods of using any of the nucleic acid fragments or polypeptide fragments, Applicants are permitted to elect a single sequences (See MPEP 803.04).

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

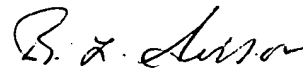
11. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS